

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
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THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	CIVIL ACTION NO. 99-20593
v.)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

8926

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, J.

August 17, 2012

Patricia Drennen ("Ms. Drennen" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered to be eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.³ See Settlement Agreement §§ IV.B.1.a. & I.22.

In August, 2009, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Peter B. Frechie, M.D. Based on an echocardiogram dated February 14,

2. (...continued)
not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

2003,⁴ Dr. Frechie attested in Part II of Ms. Drennen's Green Form that she suffered from mild aortic regurgitation and aortic sclerosis.⁵ Dr. Frechie also attested that claimant had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™ and required a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery.⁶ Based on such findings, claimant would be entitled to Matrix B-1, Level IV⁷ benefits in the amount of \$112,396.⁸

4. Because claimant's February 14, 2003 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated August 13, 2002 to establish her eligibility to submit a claim for Matrix Benefits.

5. The presence of aortic sclerosis in Diet Drug Recipients who are sixty (60) years of age or older at the time they are first diagnosed as FDA Positive requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c).

6. Dr. Frechie also attested that claimant suffered from moderate mitral regurgitation, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

7. Under the Settlement Agreement, an eligible claimant is entitled to Level IV benefits if he or she has had valvular repair or replacement surgery and requires a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery. See Settlement Agreement § IV.B.2.c.(4)(g). As the Trust concedes that Ms. Drennen has met these requirements, the only issue is whether she is eligible for benefits.

8. In or around October, 2005, claimant was paid Matrix B-1, Level II benefits in the amount of \$95,377 for damage to her
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In the report of claimant's August 13, 2002 echocardiogram, the reviewing cardiologist, Jeffrey D'Andrea, D.O., stated that claimant had "trace to mild aortic regurgitation." Dr. D'Andrea, however, did not specify a percentage as to the level of claimant's aortic regurgitation. Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitating jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH").

See Settlement Agreement § I.22.

In October, 2009, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for the attesting physician's finding of mild aortic regurgitation on claimant's August 13, 2002 echocardiogram. Specifically, Dr. Oliner determined that "[t]he [aortic regurgitation] is trace, with a very thin intermittent jet."

Based on the auditing cardiologist's finding, the Trust issued a post-audit determination denying Ms. Drennen's claim.

8. (...continued)
mitral valve. According to the Trust, if entitled to Matrix B-1, Level IV benefits, claimant would be entitled to Matrix Benefits in the amount of \$207,773. The amount at issue, therefore, is the difference between the Level II Matrix Benefits already paid and the amount of Level IV Matrix Benefits.

Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁹ In support of her claim, Ms. Drennen submitted a letter from Nicholas DePace, M.D., F.A.C.C., who stated to a "[r]easonable degree of medical certainty this patient has mild aortic insufficiency, not trace." (emphasis in original). Claimant also submitted several reports from echocardiograms performed from 2003 through 2006, which she argues support her attesting physician's finding of mild aortic regurgitation on the August 13, 2002 qualifying echocardiogram.

The Trust then issued a final post-audit determination, again denying Ms. Drennen's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Drennen's claim should be paid. On August 19, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8518 (Aug. 19, 2010).

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Drennen's claim.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 17, 2010, and claimant submitted sur-reply on January 6, 2011. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that claimant's August 13, 2002 echocardiogram demonstrated at least mild aortic regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

this finding, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for this finding, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Drennen argues that there is a reasonable medical basis for finding that her August 13, 2002 echocardiogram demonstrates mild aortic regurgitation and, therefore, she is eligible to receive Level IV Matrix Benefits for damage to her aortic valve. Claimant also contends that we should ignore Dr. Oliner's findings because they are inconsistent with the findings of Vince Sorrell, M.D., the cardiologist who audited her prior claim for Level II benefits based on damage to her mitral valve.¹¹

In response, the Trust argues that neither claimant nor Dr. DePace addresses or rebuts the specific findings of the auditing cardiologist, Dr. Oliner. The Trust also claims that Ms. Drennen cannot demonstrate a reasonable medical basis for her claim simply by "collect[ing] more opinions." Finally, the Trust asserts that the audit of Ms. Drennen's initial claim, based on

11. Ms. Drennen also argues that she is not required to prove separately that she was diagnosed with mild or greater aortic regurgitation before the end of the Screening Period because she was "deemed eligible to receive future matrix benefits" based on her mitral valve claim, "despite the fact the [subsequent claim] was on a different valve." We disagree. See Settlement Agreement §§ IV.B.2.h.-j.

her mitral valve, is irrelevant to the audit of her current claim.

The Technical Advisor, Dr. Abramson, reviewed claimant's August 13, 2002 echocardiogram and concluded that there was a reasonable medical basis for finding mild aortic regurgitation. In particular, Dr. Abramson determined that:

The parasternal views are so technically limited that I cannot visualize any aortic regurgitation or the number of aortic cusps. On the apical views, there is a tiny jet of aortic regurgitation. JH/LVOTH is a gross estimate of aortic regurgitation and is very difficult to measure, especially in the apical views in poor quality images. The jet in this Claimant is very difficult to measure, but it is not unreasonable to interpret it as mild aortic regurgitation.

....

In summary, I would interpret the severity of the aortic regurgitation on the echocardiogram of August 13, 2002 as trace, but it is not unreasonable to interpret it as mild. There is a reasonable medical basis for the physician completing the diet-drug recipient's claim form to state that Patricia Drennen has mild aortic regurgitation on the August 13, 2002 echocardiogram.

After reviewing the entire Show Cause Record, we find that claimant is eligible to receive Matrix Benefits based on damage to her aortic valve. The Settlement Agreement states that the following Class Members are eligible to receive Matrix Benefits:

Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of

the Screening Period and who have registered for further settlement benefits by [May 3, 2003].

Settlement Agreement § IV.B.1.a. The Settlement Agreement further defines "FDA Positive" as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." See id. § I.22. Thus, claimant must establish at least mild aortic regurgitation to be eligible to seek Matrix Benefits for a claim based on her aortic valve.

While Dr. Oliner determined that Ms. Drennen's echocardiogram only demonstrated trace aortic regurgitation, Dr. DePace explained that Ms. Drennen's aortic regurgitation was mild. In reviewing the Show Cause Record, the Technical Advisor, Dr. Abramson, also concluded that, while she would interpret the severity of the aortic regurgitation on claimant's August 13, 2002 echocardiogram as trace, "[t]here is a reasonable medical basis for the physician completing the diet-drug recipient's claim form to state that Patricia Drennen has mild aortic regurgitation." Despite an opportunity to do so, the Trust did not refute or respond to Dr. Abramson's conclusions.

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim. Therefore, we will reverse the Trust's denial of Ms. Drennen's claim for Matrix B-1, Level IV benefits.